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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|----------------------------|----------------------|--------------------------|------------------|--|
| 10/595,798 | 05/12/2006 | David Anthony Barda | X16511 6910 | | |
| 25885 ELI LILLY & | 7590 09/06/2001 COMPANY | 1 | EXAMINER | | |
| PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288 | | | DAVIS, ZINNA NORTHINGTON | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1625 | | |
| | | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE | |
| | | | 09/06/2007 | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

| | | Application No. | Applicant(s) | | | |
|---|---|----------------------------|--|--|--|--|
| Office Action Summary | | 10/595,798 | BARDA ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Zinna Northington Davis | 1625 | | | |
| | The MAILING DATE of this communication app | - | orrespondence address | | | |
| Period fo | • • | / IO OFT TO EVEIDE AMONTHY | 0) 5004 | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| | Status | | | | | |
| 1) | Responsive to communication(s) filed on | | | | | |
| 2a)□ | ,— | s action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | |
| _ | 4)⊠ Claim(s) <u>1-11</u> is/are pending in the application. | | | | | |
| • | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | |
| 6) | 6) Claim(s) is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) 1-11 are subject to restriction and/or election requirement. | | | | | | |
| Applicati | ion Papers | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 2) Notice | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal F | r (PTO-413) Paper No(s) Patent Application (PTO-152) | | | |

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Election/Restrictions

1. Claims 1-11 are pending.

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 11, drawn to a chemical compound and a pharmaceutical composition of formula I.
 - II. Claim 10, method for treatment of susceptible neoplasms using a chemical compound of formula I.
- 3. Inventions I-II are related as product claims. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP \ni 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. At pages 9 and 10 of the specification, susceptible neoplasm refers to abnormal growth of tissue of many disorders.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. The examiner has required restriction between product and process claims.

 Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

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with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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- 6. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.
- 7. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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8. A telephone call was made to Danica Hostettler on August 28, 2007 to request

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an oral election to the above restriction requirement, but did not result in an election

being made.

9. Applicant is advised that the reply to this requirement to be complete must

include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims

encompassing the elected invention.

10. The election of an invention or species may be made with or without traverse. To

reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the

election shall be treated as an election without traverse.

11. Should applicant traverse on the ground that the inventions or species are not

patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection

under 35 U.S.C.103(a) of the other invention.

12. Applicant is advised that the reply to this requirement to be complete must

include an election of the invention to be examined even though the requirement be

traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected

invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by

a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37

CFR 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Zinna N. Davis whose telephone number is 571-272-

0682. The examiner can normally be reached on M-F.

15. The fax phone numbers for the organization where this application or proceeding

is assigned are 571-273-8300 for regular communications.

16. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner

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znd 08.28.2007